DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021372

NOTIFICATION OF NON-COMPLIANCE WITH PREA

Helsinn Healthcare SA
c/o August Consulting, Inc.
Attention: Craig Lehmann, Pharm.D.
Authorized Representative
515 S. Capital of Texas Hwy., Suite #150
Austin, TX 78746

Dear Dr. Lehmann:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Aloxi (palonosetron hydrochloride) Injection, which was approved on July 25, 2003.

The Agency has determined that you have failed to meet the requirements of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessments, which were deferred until July 31, 2008. Therefore, we are hereby notifying you that due to your failure to submit either the pediatric assessments or a request for a deferral extension, you are not in compliance with federal law.

Under the provisions of title V, section 505, of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), you must respond in writing within forty-five calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable. In accordance with FDASIA, FDA will post this letter and your response on the website located at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your NDA with a cross-reference letter to the IND to which your protocol has been submitted. In addition, send a copy of the cover letter to CDER's Pediatric and Maternal Health Staff.

If you have any questions, call Jagjit Grewal, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology & Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

DONNA J GRIEBEL
04/11/2013